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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,825	01/23/2004	Jan Weber	1001.2246101	5021
28075 7590 11/24/2009 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER				
MCEVOY, THOMAS M				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
11/24/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/763,825

Applicant(s)

WEBER ET AL.

Examiner

Thomas McEvoy

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-24, 26-28, 30-38, 43, 50-59, 61-63, 65, 66, 69-76 and 78-87 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-13, 15, 16, 24, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74 and 80-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of Priorities Claimed (PTO-402)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,43,51,53,55,58,59,62,65,66,69,70,75,76,78 and 79.

DETAILED ACTION

1. Currently claims 1-4, 7-24, 26-28, 30-38, 43, 50-59, 61-63, 65, 66, 69-76 and 78-87 are pending. Claims 7, 8, 14, 17-23, 26, 27, 33, 43, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, 75, 76, 78 and 79 have been withdrawn. Claims 5, 6, 25, 29, 39-42, 44-49, 60, 64, 67, 68 and 77 have been cancelled. Claims 1-4, 9-13, 15, 16, 24, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74 and 80-87 are considered below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 9-11, 12, 13, 15, 16, 24, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74 and 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) in view of Couvillon (US 2003/0236531).

Regarding claims 1, 4, 12, 13, 15, 16, 28, 36, 37, 50, 52, 54, 56, 57, 61, 71, 72 and 84, Maseda discloses a medical catheter comprising (a) an elongate body 114 adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; (b) a balloon 118; and (c) an active region (magnified section, Figure 5) comprising a conductive polymer 500 disposed over the elongate body. Maseda fails to specifically disclose other types of electroactive polymers, such as those which are actuated by volumetric expansion, but clearly indicates that the electroactive polymer used in his disclosure is for explanatory purposes only (col. 4, lines 44-48). Couvillon

discloses the device as previously made of record where the electroactive polymer strands expand the end of the device in much the same way as a balloon (Figures 2, 7 and 8) which can overcome the stress exerted by smooth muscle cells (paragraph 0039). Couvillon discloses that the electroactive polymer strips can expand a balloon-like structure (Figure 2B) in a continuous band (except for being interrupted by aperture 103; Figures 2A-B). Maseda discloses: the electroactive polymer strands may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3- 6); the circumferentially arranged band of composite strands expands and functions like a balloon (col. 6, lines 47-59); the balloon itself may incorporate the composite strands (col. 8, lines 6-9). It would have been obvious to one of ordinary skill in the art in view of Couvillon that the Maseda device could be expanded by volumetrically expanding electroactive polymers because they would be effective at overcoming the stress of smooth muscle that lines vessel walls when dilating a vessel or maneuvering the catheter within a vessel. It would have been obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the above suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture). Furthermore, since Maseda discloses that the strands can be contained within recesses of the outer tube 114 (col. 5, line 61), it would also have been obvious to one of ordinary skill in the art to have attached the strands within recesses of tube 116 in order to expand the balloon; using the same structure shown in

Figure 5 as a framework (i.e. the balloon+longitudinal strips are the circumferential band; this at least meets the claim 1 and 28 limitations).

Regarding claims 2 and 3, Maseda as combined with Couvillon would use multiple radially expanding bands to expand the balloon (either using the multiple circumferential bands of Couvillon or the multiple longitudinal bands of Maseda).

Regarding claims 9-11 and 38, as explained above, Couvillon teaches that circumferentially oriented electroactive polymer strips can be placed within or under a balloon-like member to expand it (Examiner considers it fully disclosed that the continuous circumferential band 102/110 of Figure 6 is intended to expand the Figure 2/3 capture device 100 from within as depicted in Figure 6). Maseda discloses using any variety of strip geometries (col. 8, lines 12-17), placed within the outer or inner tubular member (col. 8, lines 4-7; col. 5, lines 56-61; col. 6, lines 56-58). It would have been obvious to one of ordinary skill in the art to have incorporated the electroactive polymer actuator strips beneath, within or within recesses of the balloon of Maseda or the inner tube 116, and to have oriented them longitudinally as disclosed by Maseda (i.e. the balloon+longitudinal strips are the circumferential band and the recess is the portion under the balloon where the outer tubular member ends and the elongate body is narrowed or recessed), or circumferentially as disclosed by Couvillon (again the recess being as just described above).

Regarding claims 24, 73, 74 and 80, if the balloon is expanded by the electroactive polymer strips of Couvillon as described above, the balloon would be stiffened, in a similar manner as disclosed for Applicant's balloon.

Regarding claims 30-32 and 34, in the modified balloon of Maseda as described above, the active region would be able to radially expand the entire balloon, both proximal and distal portions. The electroactive strips of Couvillon volumetrically expand when actuated.

Regarding claim 35, Maseda discloses that the electroactive polymer strips can be incorporated into the catheter tube and then the entire tube is expanded (col. 7, line 58 to col. 8, line 2). It would have been obvious to one of ordinary skill in the art to have expanded the inner tube 116 in this manner in order to expand the balloon because of the suggestions made by Maseda as explained above. In particular, Maseda suggests incorporating the electroactive polymer strips into the balloon (col. 8, lines 8-9).

Regarding claim 63, the insertable body 114 can be extruded (col. 5, line 61).

Regarding claims 80-83 and 86, in the modified balloon of Maseda in view of Couvillon as described above, the active region would be sealed by the balloon if the active region is installed within, beneath or within a recess of the balloon. The electroactive strips of Couvillon incorporate an electrolyte and a counter electrode (Figure 1).

4. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) and Couvillon (US 2003/0236531) in view of Sharrow (US 4,793,359).

Regarding claim 87, Maseda as modified by Couvillon discloses the invention as described above comprising a plurality of active regions, where an active region can be one of the electroactive polymer actuator strips and where it would have been obvious to incorporate the strips within, underneath or within a recess of the balloon or inner

tubular member 116. Maseda fails to disclose that a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band. Sharrow teaches that a balloon in a balloon catheter can have two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon (col. 4, lines 4-5). It would have been obvious to one of ordinary skill in the art to have incorporated two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon.

Response to Arguments

5. Applicant's arguments filed July 28th 2009 have been fully considered but they are not persuasive. Applicant has argued several points throughout the response which Examiner believes can be summarized as follows: 1) Couvillon does not disclose a balloon being expanded by conductive polymers; 2) since Maseda is concerned with the expansion of a balloon and Couvillon is not, it would not be appropriate to modify Maseda's balloon with the strips of Couvillon; 3) Couvillon and Maseda do not teach a continuous circumferential band as claimed; 4) since Couvillon does not disclose a continuous circumferential band, it would not be appropriate to provide Couvillon's bands in a continuous configuration even if it were proper to modify Maseda's balloon with Couvillon's band; 5) Couvillon and Maseda do not teach conductive polymers underneath a deformable structure or balloon in order to expand it.

In regard to arguments 1 and 2, Examiner believes that since Maseda suggests modifying the balloon with conductive polymers but does not give any detailed configurations for doing so, one of ordinary skill in the art would look to any balloon like structure which incorporates electroactive polymers as a possible teaching to modify the Maseda balloon. Examiner believes the capture device of Couvillon is very structurally related to Maseda's balloon. It expands in a very similar manner as a balloon and is intended to overcome the constriction of a blood vessel in order to be fully expanded; much like the dilating balloon of Maseda. One of ordinary skill in the art would recognize these similarities and would also recognize that the strips of Couvillon could easily be modified to expand the balloon of Maseda. In regard to arguments 3 and 4, Examiner believes that if it is appropriate to modify Maseda's balloon with the longitudinal strips of Figure 5A as a framework for expansion, then the limitations of at least claims 1 and 28 are met (when using Couvillon's volumetrically expanding electroactive polymer material) as described in additional detail above. If incorporating Couvillon's strips into the balloon of Maseda instead, one of ordinary skill in the art would recognize that there is no need to make the strips discontinuous since there is no aperture. One of ordinary skill in the art would recognize that making the strips circumferentially discontinuous would result in uneven expansion of the balloon. In regard to argument 5, Examiner has explained in detail above how Couvillon does disclose the electroactive polymer strips being beneath a deformable structure in order to expand it. Examiner has also explained how it would be obvious to one of ordinary skill in the art that the expanding strips of Figure 5A (of Maseda) are clearly suitable as

a framework for expanding a balloon from underneath. Given Maseda's suggestion to incorporate the electroactive polymers in/on the balloon in order to expand it, this modification would be even more obvious.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is 571-270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/21/09